REMARKS/ARGUMENTS:

Claims 9-18 remain in this application.

Amendments to the Specification and the Claims correct typographical errors and clarify chemical names.

Claim Rejections under 35 USC § 112, second Paragraph:

Claims 13, 17 and 18 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite.

Regarding claim 13, the Examiner requested recitation of terms "ICI 1643,384" and "ICI 182,780" and indicated that the term "main metabolite of tamoxiphen" was unclear. Applicants have amended claim 13 to clarify terms and recite the chemical names of "ICI 1643,384" and "ICI 182,780", which are "7α-[9-[*N*-butyl-*N*-methylaminocarbonyl]decyl]estra-1,3,5(10)-triene-3,17β-diol" and "7α-[9-[4,4,5,5,5-pentafluoropentyl)sulfonyl]nonyl]estra-1,3,5(10)-triene-3,17β-diol", respectively.

Regarding claims 17 and 18, Applicants have provided the correct chemical names for PEF and OPP materials.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112 are respectfully requested.

Claim Rejections under 35 USC § 103:

Claims 9-18 were rejected under 35 U.S.C. § 103(a) as obvious over WO 96/11670 in view of Jalonen (5,571,534) by itself or in further combination with Grunicke (5,770,593).

Claims 9-18 were also rejected under 35 U.S.C. § 103(a) as obvious over either DE 44 08 011 or DE 41 32 345 or Arndt (Breast Cancer Research and Treatment, 1997) in view of Jalonen (5,571,534) by itself or in further combination with Grunicke (5,770,593).

Applicants respectfully traverse these rejections.

As to the first § 103(a) rejection, WO 96/11670 teaches liposomal compositions containing a phospolipid, ether lipid, PEG derivatized lipid and an additional antineoplastic agent. However, these compositions do not include tamoxifen.

Jalonen discloses liposomal compositions containing lipids, cyclodextrin and tamoxifen. Jalonen teaches at Col. 3, line 49 et seq. that cyclodextrin is needed to form a complex with the drug in order to achieve stable liposomes. Jalonen concludes that "stable liposomes cannot be achieved in the absence of a cyclodextrin component..." (Col. 3, line 61). Thus, Jalonen teaches away from Applicants' composition which does not include cyclodextrin. Therefore, there is no reasonable expectation of success of using the teaching of Jalonen to make Applicants' compositions. This is especially true because WO96/11670 teaches the use of ether lipids, while Applicants' compositions are made with alkylphospholipids. Without a reasonable expectation of success of using the teachings of Jalonen to make Applicants' compositions, Applicants' claimed compositions are not obvious over WO 96/11670 in view of Jalonen.

Grunicke teaches theraputic use of tamoxifen in solid or liquid forms other than liposomes. To establish a prima facie case for obviousness the Examiner must show a reasonable expectation of success. M.P.E.P. 2143. Because Grunicke teaches use of tamoxifen only in solid or liquid forms other than liposomes, there is no reasonable expectation of success of using the teaching of Grunicke in combination with WO 96/11670 and Jalonen to make Applicants' liposome formulation.

Thus, claims 9-18, as listed herein, are not obvious under 35 U.S.C. § 103(a) over WO 96/11670 in view of Jalonen (5,571,534) by itself or in further combination with Grunicke (5,770,593).

As to the second § 103(a) rejection, none of DE 44 08 011, DE 41 32 345, and Arndt teach liposomal compositions which include tamoxifen.

As discussed above, Jalonen teaches away from liposomal compositions containing an anti-estrogen and a phospholipid which do not include cyclodextrin. Since Applicants' compositions do not include cyclodextrin, there is no reasonable expectation of success of using the teachings of Jalonen in combination with any of DE 44 08 011, DE 41 32 345, or Arndt alone, or in further combination with Jalonen to make Applicants' compositions.

Grunicke teaches therapeutic use of tamoxifen in various solid or liquid forms, but not in liposomes. Therefore, there is no reasonable expectation of success of using the teaching of Grunicke in combination with DE 44 08 011, DE 41 32 345, or Arndt to make Applicants' liposome formulation.

Accordingly, claims 9-18, as listed, are not obvious under 35 U.S.C. § 103(a) over either DE 44 08 011 or DE 41 32 345 or Arndt (1997) in view of Jalonen (5,571,534) by itself or in further combination with Grunicke (5,770,593).

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.

Conclusion:

Based on the foregoing amendments and remarks, favorable consideration and allowance of claims 9-18 as listed herein are respectfully requested.

Should the Examiner require or consider it advisable that the specification, claims and/or drawings be further amended or corrected in formal respects in order to place the case in condition for final allowance, then it is respectfully requested that such amendment or correction be carried out by Examiner's Amendment and the case passed to issue.

Alternatively, should the Examiner feel that a personal discussion might be helpful in advancing this case to allowance, the Examiner is invited to telephone the undersigned.

The Commissioner is authorized to charge any required fees, including any extension and/or excess claim fees, any additional fees, or credit any overpayment, to Goodwin Procter LLP Deposit Account No. 06-0923.

Respectfully submitted for Applicants,

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